REMARKS

AMENDMENTS TO THE SPECIFICATION

The paragraph at page 3, line 12 of the specification has been amended to correct a typographical error. The preferred ratio referred to as "0.9/1.5" has been amended to correctly identify the range of "0.9-1.5." Applicants respectfully submit that no new matter has been introduced by the amendment. The amendment is supported by the specification, for example, at page 3, lines 5-11 wherein EPA/DHA ratios of from 0.88 to 2.4 are specified.

CLAIM AMENDMENTS

Claims 12-14, 18-20, 24-25 and 27-28 are amended in this Amendment C to improve form and to correct typographical errors. No new matter has been added. The amended claims are supported by the specification and by the claims as originally filed.

Claim 18 is amended to more particularly define the invention. More specifically, the amended claim is directed to a method for preventing mortality or sudden death caused by reoccurrence of myocardial infarction in a patient who is a survivor of myocardial infarction. The amended claim is supported in the specification, for example, at page 2, lines 11 to 15.

Claims 17 and 23 have been canceled without prejudice. New claims 30-35 have been added to more particularly define the invention. Support for the new claims can be found in the specification, for example, at page 3, lines 5-11. Upon entry of this amendment, claims 12-14, 16-20, 22, 24-25, 27-28 and 30-35 will be pending in the application.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 18-20, 22 and 23 stand rejected under 35 U.S.C. § 112, first paragraph for failing to provide enablement for the prevention of mortality or sudden death in general for patients having suffered from myocardial infarction. This rejection is respectfully traversed. As described above, Applicants have amended claim 18 to be directed to "a method for preventing mortality or sudden death caused by the reoccurrence of myocardial infarction . . ." to obviate the rejection. The claim as amended is enabled by the specification at page 2, lines 11-15. Withdrawal of the rejection is respectfully requested.

REJECTION UNDER 35 U.S.C. § 103

Claims 12-14, 16-20, 22-25, and 27-28 stand rejected under 35 U.S.C. § 103(a) as being obvious over Breivik et al. (U.S. Pat. No. 5,502,077) in view of Garrison et al. (The Nutrition Desk Reference). This rejection is respectfully traversed.

As defined in independent claims 12, 18, 24 and 27, the present invention is directed to the use of essential fatty acids with a high content in EPA-ethyl ester, DHA-ethyl ester or a high concentration mixture of EPA-ethyl ester and DHA-ethyl ester for the prevention of mortality or sudden death due to the reoccurrence of cardiovascular events in patients who have suffered from a myocardial infarction. In particular, 80% of patients who have survived a myocardial infarction and exhibit low ventricular ejection fractions are at high risk of sudden death or reinfarction. See page 4, lines 19-21 of the specification. However, as described at page 3, line 15 to page 4, line 15 of the specification, Applicant conducted a lengthy clinical trial wherein the administration of compositions containing a high concentration mixture of EPA-ethyl ester and DHA-ethyl ester to myocardial infarction survivors showed "a surprising and highly significant reduction in post-infarction mortality." Accordingly, the present invention provides a novel therapeutic tool for preventing sudden death in patients who have suffered a myocardial infarction.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the teachings of prior art references; and the references, when combined, must teach all of the claim limitations. See MPEP 2143. Further, the prior art or knowledge generally available in the art must provide a reasonable expectation of success and the teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on applicant's disclosure. See Id.; In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The principal reference, Breivik et al., describes fatty acid compositions containing a concentration of at least about 80% by weight of omega-3 fatty acids. The compositions are described as useful in the treatment of cardiovascular risk factors such as hypertension, hypertriglyceridemia and high coagulation factor VII phospholipids complex activity. However, as described at Col. 6, lines 20-37, Breivik et al. studied the administration of fatty acid

compositions on a narrow population of otherwise healthy Norwegians with untreated moderate hypertension and no previous cardiac illness or cardiac drug use. Nothing in the reference describes the treatment of patients having suffered from a myocardial infarction. Further, nothing in the reference remotely teaches or suggests what effect, if any, the compositions would have if administered to myocardial infarction survivors. Thus, it is respectfully submitted that the cardiovascular risk factors described in Breivik et al. bear little relevance on the methods of the present invention which are directed to preventing mortality or sudden death by the reoccurrence of cardiovascular events in a patient who has survived a myocardial infarction.

Further, it is respectfully submitted that the deficiencies of the primary reference cannot be overcome by resort to the teachings of Garrison et al. Garrison et al. merely list myocardial infarction or "heart attack" as a cardiovascular disease without providing any further teaching of relevance to the primary reference with respect to the methods of the present invention. Thus, it is respectfully submitted that nothing in the prior art teaches or suggests the prevention of mortality or sudden death by the reoccurrence of cardiovascular events in a patient who is a survivor of myocardial infarction as required by the methods of the instant invention. Accordingly, Applicant respectfully submits that a *prima facie* case of obviousness cannot be shown and that the present invention is patentable over the cited references Breivik et al. in view of Garrison et al. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

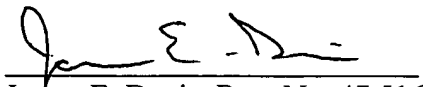
CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot by this amendment. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314) 446-7683.

Applicants do not believe that any fee is required by the timely submission of this response. However, the Commissioner is hereby authorized to charge any required fees to

Deposit Account No. 08-0750. Further, if there is any other fee deficiency or overpayment of any fees in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or credit such overpayment to Deposit Account No. 08-0750.

Respectfully submitted,



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